Media & Investor Release

Roche's collaborator MediLink announces phase III data for Tam-Peli showing significantly improved overall survival in Chinese patient population with relapsed small-cell lung cancer

- **Tambotatug pelitecan (Tam-Peli) demonstrated statistically significant efficacy over topotecan in a phase III study conducted in China, reducing the risk of death by 54% and disease progression by 71%, while achieving an objective response rate of 59.1% vs 9.7%[1]**
- **The novel B7-H3-targeted antibody-drug conjugate with a dual release mechanism of the payload is based on MediLink's proprietary TMALIN® platform, designed to maximise antitumour activity while minimising off-target toxicity[2,3]**
- **Roche is developing and commercialising Tam-Peli outside mainland China, Hong Kong, and Macau across multiple tumour types, with plans to rapidly initiate global trials**
- **Tam-Peli has received U.S. FDA and China CDE Breakthrough Therapy Designations for relapsed small-cell lung cancer (SCLC)**

Basel, 13 September 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) today announced that its collaborator MediLink released interim results from the randomised phase III TAISHAN-302 trial evaluating Tam-Peli (tambotatug pelitecan, YL201) versus topotecan in Chinese patients with relapsed small-cell lung cancer (SCLC) who progressed after prior platinum-based chemotherapy with or without a PD-L1 inhibitor.[1] The trial met its primary endpoint of overall survival (OS) with Tam-Peli demonstrating a statistically significant and clinically meaningful OS benefit, reducing the risk of death by 54% (median OS 13.3 vs. 9.4 months; stratified HR=0.46; p<0.0001). Tam-Peli also showed robust efficacy across secondary endpoints, significantly extending progression-free survival (PFS) (median PFS 7.4 vs. 2.8 months) and response rates (59.1% vs. 9.7%) compared to standard-of-care topotecan.[1]

The trial results are being presented as a Late-Breaking Abstract during a Presidential Presentation at the International Association for the Study of Lung Cancer (IASLC) 2026 World Conference on Lung Cancer (WCLC) in Seoul with simultaneous publication in The New England Journal of Medicine.[1] Additionally, the Center of Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has accepted the New Drug Application (NDA) for filing.

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"The second positive phase III trial for Tam-Peli, TAISHAN-302, reinforces our confidence in its potential to improve outcomes for people with cancer," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "These data demonstrate clinically meaningful survival and response rate improvements in an aggressive and hard-to-treat disease, supporting our plans to initiate global phase III trials quickly."

Key efficacy results from the phase III TAISHAN-302 trial[1]

Primary and key secondary endpoints	**Tam-Peli (n=225)**	**Topotecan (n=226)**	**Hazard Ratio / (95% CI)**	**p-value**
Median OS in months	13.3	9.4	HR 0.46 (0.35–0.62)	p < 0.0001
Median PFS in months	7.4	2.8	HR 0.29 (0.23–0.37)	p < 0.0001
Confirmed Objective Response Rate (%)	59.1	9.7	–	p < 0.0001

Consistent OS and PFS improvements were observed across prespecified subgroups, including age, chemotherapy-free interval (<90 vs. ≥90 days), and baseline liver or brain metastatic status. In patients with baseline brain metastases, Tam-Peli extended median intracranial PFS (6.1 months vs. 4.2 months; unstratified HR=0.43; 95% CI: 0.27–0.68) and achieved a higher intracranial response rate (32.4% vs. 2.9%).[1]

Tam-Peli showed a favourable and manageable safety profile, demonstrating lower rates of Grade ≥3 treatment-related adverse events (TRAEs) compared with topotecan (46.4% vs. 74.7%). Serious TRAEs occurred in 25.9% of patients receiving Tam-Peli versus 36.4% with topotecan. Treatment-emergent interstitial lung disease (ILD/pneumonitis) across all grades occurred in 4.9% of Tam-Peli patients versus 1.4% with topotecan; grade 3 ILD/pneumonitis events were low in both groups (0.9% each), with no Grade 4 or 5 events reported.[1]

Tam-Peli is designed to target B7-H3, a protein broadly expressed in solid tumours but minimally in normal tissue, allowing it to target cancer cells with high selectivity. Built on MediLink's TMALIN® platform, its stable linker and dual-release mechanism are designed to maximise therapeutic efficacy while limiting off-target toxicity.[2,3]

Following the positive phase III TAISHAN-301 trial (NCT06629597) in nasopharyngeal carcinoma, TAISHAN-302 represents the second positive phase III readout for Tam-Peli,

conducted in patients in China. Under a collaboration and exclusive licensing agreement between Roche and MediLink Therapeutics, Roche holds development, manufacturing, and commercialisation rights for Tam-Peli worldwide, outside mainland China, Hong Kong, and Macau. Roche is advancing clinical development in its licensed territories across multiple solid tumour types and plans to rapidly initiate global phase III trials.

About the TAISHAN-302 study

TAISHAN-302 (NCT06612151) is a randomised, open-label phase III study evaluating the efficacy and safety of Tam-Peli (2.0 mg/kg intravenously on day 1 of each 21-day cycle, maximum dose 200 mg) compared with topotecan in patients with small-cell lung cancer (SCLC) who have progressed after one prior line of platinum-based chemotherapy with or without a PD-L1 inhibitor. The trial enrolled 451 patients across 85 study sites in China. The primary endpoint of the trial is overall survival (OS). Key secondary endpoints include investigator-assessed progression-free survival (PFS) and objective response rate (ORR), alongside disease control rate (DCR), duration of response (DoR), time to response (TTR), safety, pharmacokinetics, and immunogenicity.[1]

About tambotatug pelitecan (Tam-Peli; YL201)

Tambotatug pelitecan (Tam-Peli; YL201) is an investigational antibody-drug conjugate (ADC) targeting B7-H3, a protein highly expressed across various solid tumours, both on the tumour cells and in the microenvironment, but limited in healthy tissues.[1,2] Utilising MediLink Therapeutics' TMALIN® (Tumour Microenvironment-Activatable Linker) platform, Tam-Peli links a B7-H3-specific monoclonal antibody to a novel topoisomerase 1 inhibitor payload with a drug-to-antibody ratio (DAR) of 8. By combining a stable, hydrophilic linker with a dual-release mechanism, Tam-Peli is designed to deliver its cytotoxic payload both inside tumour cells as well as extracellularly in the tumour microenvironment, maximising therapeutic efficacy while minimising systemic toxicity.[2,3]

Beyond SCLC, Tam-peli holds two U.S. Food and Drug Administration (FDA) Orphan Drug Designations and three China Center of Drug Evaluation (CDE) Breakthrough Therapy Designations (BTDs) across additional indications, including nasopharyngeal carcinoma (NPC), esophageal squamous cell carcinoma (ESCC), and pancreatic cancer.

In January 2026, Roche entered into an exclusive licensing agreement with MediLink Therapeutics for the development, manufacturing, and commercialisation of Tam-Peli worldwide, excluding mainland China, Hong Kong SAR and Macau.

About Roche in lung cancer

Lung cancer remains the leading cause of cancer-related deaths worldwide, surpassing the combined mortality rates of breast, prostate, and stomach cancers. Each year, it claims the lives of 1.8 million people. SCLC accounts for 15% of lung cancer diagnoses.[4] It is a highly

aggressive form of lung cancer which progresses rapidly, regardless of the stage of disease at diagnosis. Despite advances in first-line treatment, SCLC frequently relapses or progresses and outcomes remain poor for many people with recurrent disease, highlighting the continued need for more effective treatment options.

Roche is committed to advancing the field of lung cancer treatments, leveraging more than 20 years of scientific expertise to improve patient outcomes. Roche's portfolio includes approved medicines such as Alecensa® (alectinib), Tecentriq® (atezolizumab), and Rozlytrek® (entrectinib). Its extensive pipeline includes investigational treatments across three key focus areas: small-cell lung cancer, non-small cell lung cancer (NSCLC) with actionable genomic alterations (AGA), and NSCLC without AGA.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions. Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.
Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

For more information, please visit www.roche.com.

References

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